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Patent Docket P1089R1C1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of Lam et al. Serial No.: 09/724,868 Filed: 28 November 2000 For: ANTIBODY FORMULATION | Group Art Unit: Unassigned Examiner: Unassigned CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on February 13, 2001 <i>Ann Savelli</i> Ann Savelli |
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INFORMATION DISCLOSURE STATEMENTAssistant Commissioner of Patents
Washington, D.C. 20231

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Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☒ 37 CFR §1.97(b)

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☐ 37 CFR §1.97(c)

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

☐ 37 CFR §1.97(d)

- after the period specified in CFR §1.97(c), and is accompanied by the fee set forth in 37 CFR §1.17(p) and a statement as specified in 37 CFR §1.97(e), as checked below.

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[If either of boxes 37 CFR §1.97(c) or 37 CFR §1.97(d) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR §1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR §1.704.
- ☐ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. 09/097,171, filed June 6, 1998 and relied upon in this application for an earlier filing date under 35 USC §120.

☐ BLAST results enclosed:

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1- A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

- ☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR §1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR §1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

In the event that the Office determines a fee to be due where none is specifically authorized in this paper, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR §1.17(p).

Respectfully submitted,

GENENTECH, INC.

Date: February 13, 2001

By: Lee Tan

Lee K. Tan

Reg. No. 39,447

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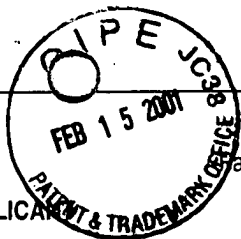
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PATENT TRADEMARK OFFICE

FORM PTO-1449

U.S. Dept. of Commerce
Patent and Trademark OfficeAtty Docket No.
P1089R1C1Serial No.
09/724,868

LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant
Lam et al.Filing Date
28 Nov 2000Group
Unassigned

U.S. PATENT DOCUMENTS

| Examiner Initials | | Document Number | Date | Name | Class | Subclass | Filing Date |
|----------------------|-----|-----------------|----------|-------------------------|-------|----------|-------------|
| | * 1 | 4,093,606 | 06.06.78 | Coval, M. | | | |
| | * 2 | 4,457,916 | 03.07.84 | Hayashi et al. | | | |
| | * 3 | 4,499,073 | 12.02.85 | Tenold, R. | | | |
| | * 4 | 4,877,608 | 31.10.89 | Lee, T. et al. | | | |
| | * 5 | 4,940,782 | 10.07.90 | Rup et al. | | | |
| | * 6 | 5,032,405 | 16.07.91 | Huang, H. et al. | | | |
| | * 7 | 5,036,049 | 30.07.91 | Audhya, T. et al. | | | |
| | * 8 | 5,096,885 | 17.03.92 | Pearlman et al. | | | |
| | * 9 | 5,147,637 | 15.09.92 | Wright et al. | | | |
| | *10 | 5,149,653 | 22.09.92 | Roser | | | |
| | *11 | 5,215,743 | 01.06.93 | Singh, M. et al. | | | |
| | *12 | 5,262,296 | 16.11.93 | Ogawa, E. et al. | | | |
| | *13 | 5,307,640 | 03.05.94 | Fawzy et al. | | | |
| | *14 | 5,399,670 | 21.03.95 | Bhattacharya, P. et al. | | | |
| | *15 | 5,506,342 | 09.04.96 | Reno et al. | | | |
| | *16 | 5,580,856 | 03.12.96 | Prestrelski et al. | | | |
| | *17 | 5,589,167 | 31.12.96 | Cleland et al. | | | |
| | *18 | 5,608,038 | 04.03.97 | Eibl et al. | | | |
| | *19 | 5,654,403 | 05.08.97 | Smith et al. | | | |
| | *20 | 5,730,980 | 24.03.98 | Ulevitch et al. | | | |
| | *21 | 5,736,137 | 07.04.98 | Anderson et al. | | | |
| | *22 | 5,770,700 | 23.06.98 | Webb et al. | | | |

RECEIVED

APR 02 2001

TECH CENTER 1600/2900

FOREIGN PATENT DOCUMENTS

| Examiner Initials | | Document Number | Date | Country | Class | Subclass | Translation Yes No | |
|----------------------|-----|-----------------|----------|-----------------------------|-------|----------|-----------------------|--|
| | *23 | AU-B-30771/89 | 07.09.89 | AUSTRALIA | | | | |
| | *24 | 2,138,853 | 29.06.95 | CANADA | | | | |
| | *25 | 303,746 | 22.02.89 | EPO | | | | |
| | *26 | 391,444 | 10.10.90 | EPO | | | | |
| | *27 | 661,060 | 05.07.95 | EPO (WITH ENGLISH ABSTRACT) | | | | |
| | *28 | WO 89/09402 | 05.10.89 | PCT (WITH ENGLISH ABSTRACT) | | | | |
| | *29 | WO 89/11297 | 30.11.89 | PCT | | | | |
| | *30 | WO 90/11091 | 04.10.90 | PCT | | | | |
| | *31 | WO 92/22653 | 23.12.92 | PCT | | | | |
| | *32 | WO 94/11026 | 26.05.94 | PCT | | | | |
| | *33 | WO 94/26302 | 24.11.94 | PCT | | | | |

Examiner

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Unassigned

FOREIGN PATENT DOCUMENTS

| Examiner Initials | | Document Number | Date | Country | Class | Subclass | Translation Yes No | |
|----------------------|-----|-----------------|----------|---------|-------|----------|-----------------------|--|
| | *34 | WO 96/41164 | 19.12.96 | PCT | | | | |
| | *35 | WO 97/04801 | 13.02.97 | PCT | | | | |
| | *36 | WO 97/04807 | 13.02.97 | PCT | | | | |
| | *37 | WO 97/17087 | 15.05.97 | PCT | | | | |

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

| | | | | | | | | |
|--|-----|---|--|--|--|--|--|--|
| | *38 | Akers, M., "Considerations in selecting antimicrobial preservative agents for parenteral product development" <u>Pharmaceutical Technology</u> pps. 36-40;43-44;46 (May 1984) | | | | | | |
| | *39 | Albelda et al., "Integrins and other cell adhesion molecules" <u>FASEB-J</u> 4(11):2868-2880 (1990) | | | | | | |
| | *40 | Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations" <u>Pharmaceutical Research</u> 8(3):285-291 (1991) | | | | | | |
| | *41 | Bam et al., "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique" <u>Pharm. Res.</u> 12:2-11 (1995) | | | | | | |
| | *42 | Beauvais et al., "Both Glassy State and Native Structure are Required for Storage Stability of Lyophilized Interleukin-1 Receptor Antagonist" <u>Pharm. Res.</u> (Abstract #2007) 12(9):S-80 (1995) | | | | | | |
| | *43 | Bogard et al., "Practical considerations in the production, purification, and formulation of monoclonal antibodies for immunoscintigraphy and immunotherapy" <u>Seminars in Nuclear Medicine</u> 19(3):202-220 (1989) | | | | | | |
| | *44 | Chang and Fischer, "Development of an Efficient Single-Step Freeze-Drying Cycle for Protein Formulations" <u>Pharm. Res.</u> 12(6):831-837 (1995) | | | | | | |
| | *45 | Chang et al., "Development of a Stable Freeze-dried Formulation of Recombinant Human Interleukin-1 Receptor Antagonist" <u>Pharmaceutical Research</u> 13(2):243-248 (1996) | | | | | | |
| | *46 | Chang et al., "Nucleotide sequence of the alkaline phosphatase gene of Escherichia Coli" <u>Gene</u> 44:121-125 (1986) | | | | | | |
| | *47 | Clarke et al., "Lability of Asparagine and Aspartic Acid Residues in Proteins and Peptides" <u>Stability of Protein Pharmaceuticals. Part A: Chemical and Physical Pathways of Protein Degradation</u> , T.J. Ahern and M.C. Manning, New York:Plenum Press, Chapter 1, pps. 1-29. (1992) | | | | | | |
| | *48 | Cleland and Jones, "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 22:514-515 (1995) | | | | | | |
| | *49 | Cleland et al., "Mechanisms of Nonionic Surfactant Stabilization of Proteins" <u>Pharmaceutical Research</u> (Abstract #BIOTEC 2012; Ninth Annual Meeting of the American Association of Pharmaceutical Scientists held in San Diego, CA on November 6-10, 1994) 11(10 Suppl.):S73 (1994) | | | | | | |
| | *50 | Cleland et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 10(4):307-377 (1993) | | | | | | |
| | *51 | Draber et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" <u>Journal of Immunological Methods</u> 181(1):37-43 (1995) | | | | | | |
| | *52 | Hernandez et al., "Role of neutrophils in ischemia-reperfusion-induced microvascular injury" <u>Am. J. Physiol.</u> 253(3 Pt 2):H699-H703 (1987) | | | | | | |
| | *53 | Hildreth et al., "A Human Lymphocyte-associated Antigen Involved in Cell-mediated Lympholysis" <u>European Journal of Immunology</u> 13:202-208 (1983) | | | | | | |

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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28 Nov 2000Group
Unassigned

OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

| | |
|-----|--|
| *54 | Hildreth et al., "The human lymphocyte function-associated (HLFA) antigen and a related macrophage differentiation antigen (HMac-1): functional effects of subunit-specific monoclonal antibodies" <u>J. Immunol.</u> 134:3272-3280 (1985) |
| *55 | Hynes, "Integrins: versatility, modulation, and signaling in cell adhesion" <u>Cell</u> 69(1):11-25 (1992) |
| *56 | Izutsu et al., "The effects of additives on the stability of freeze-dried β -galactosidase stored at elevated temperature" <u>Intl. J. Pharmaceutics</u> 71:137-146 (1991) |
| *57 | Jutila et al., "Inflammation-induced endothelial cell adhesion to lymphocytes, neutrophils, and monocytes" <u>Transplantation</u> 48(5):727-731 (1989) |
| *58 | Kossiakoff, A.A., "Tertiary Structure Is a Principal Determinant to Protein Deamidation" <u>Science</u> 240:191-194 (1988) |
| *59 | Lam et al., "Microencapsulation of Recombinant Humanized Monoclonal Antibody for Local Delivery" <u>American Association of Pharmaceutical Scientists, Western Regional Meeting, South San Francisco, CA</u> (Abstract #F-22 and poster presented at the meeting) (April 24-25, 1997) |
| *60 | Lam et al., "Microencapsulation of Recombinant Humanized Monoclonal Antibody for Local Delivery" <u>Proceedings of the 24th International Symposium on Controlled Release of Bioactive Materials</u> 24:759-760 (June 15-19, 1997) |
| *61 | Lam et al., "Pitfalls in Development of Multi-Dose Liquid Formulations for Three Protein Pharmaceuticals" <u>ACS National Meeting, New Orleans</u> (Abstract #137 and slides presented) (March 24-28, 1996) |
| *62 | Li et al., "Aggregation and Precipitation of Human Relaxin Induced by Metal-Catalyzed Oxidation" <u>Biochemistry</u> 34(17):5762-5772 (1995) |
| *63 | Manning et al., "Stability of Protein Pharmaceuticals" <u>Pharm. Res.</u> 6(11):903-918 (1989) |
| *64 | Mileski et al., "Inhibition of CD18-dependent neutrophil adherence reduces organ injury after hemorrhagic shock in primates" <u>Surgery</u> 108:206-212 (1990) |
| *65 | Nielsen, et al., "Stability of Freeze Dried Horseradish Peroxidase Conjugated Monoclonal Antibodies Used in Diagnostic Serology" <u>Journal of Immunoassay</u> 16(2):183-197 (1995) |
| *66 | Novak et al., "The tolerance and safety of intravenously administered benzyl alcohol in methylprednisolone sodium succinate formulations in normal human subjects" <u>Toxicology and Applied Pharmacology</u> 23(1):54-61 (Sep 1972) |
| *67 | Pearlman et al., "Analysis of Protein Drugs" <u>Peptide and Protein Drug Delivery</u> , Vincent H. L. Lee, Marcel Dekker, Inc., Chapter 6, pps. 247-301 (1991) |
| *68 | Picken et al., "Nucleotide sequence of the gene for heat-stable enterotoxin II of <i>Escherichia coli</i> " <u>Infection and Immunity</u> 42(1):269-275 (1983) |
| *69 | Pikal et al., "The Effects of Formulation Variables on the Stability of Freeze-Dried Human Growth Hormone" <u>Pharm. Res.</u> 8:427-436 (1991) |
| *70 | Pikal, M., "Freeze-Drying of Proteins, Part 2: Formulation Selection" <u>Biopharm.</u> 3(9):26-30 (1990) |
| *71 | Rao and Kroon, "Orthoclone OKT3: Chemical Mechanisms and Functional Effects of Degradation of a Therapeutic Monoclonal Antibody" <u>Stability and Characterization of Protein and Peptide Drugs: Case Histories</u> , eds. John Wang and Rodney Pearlman, New York: Plenum Press pps. 135-158, chapter 4, (1993) |
| *72 | Reilly et al., "Oral delivery of antibodies: future pharmacokinetic trends" <u>Clin. Pharmacokinet.</u> 32(4):313-323 (1997) |
| *73 | Sapan, "Immunoglobulin stability" <u>Biotechnol. Appl. Biochem.</u> 25:9-12 (1997) |

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Unassigned

*74

Scholtissek and Grosse, "A cloning cartridge of λ t₀ terminator" *Nucl. Acids Res.* 15(7):3185 (1987)

*75

Springer, T., "Adhesion receptors of the immune system" *Nature* 346:425-434 (1990)

*76

Steele et al., "Functional Capacity of Immunoglobulin G Preparations and the F(ab')₂ split product"
Journal of Clinical Microbiology 27(4):640-643 (April 1989)

*77

Stoolman, L., "Adhesion molecules controlling lymphocyte migration" *Cell* 56:907-910 (1989)

*78

Vedder et al., "A Monoclonal Antibody to the Adherence-promoting Leukocyte Glycoprotein, CD18, Reduces Organ Injury and Improves Survival from Hemorrhagic Shock and Resuscitation in Rabbits" J. Clin. Invest. 81:939-944 (1988)

*79

Wang et al., "Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers" J. Parenteral Sci. Tech. (Technical Report No. 10) 42(2S):S4-S26 (1988)

* 80

Yates, "Protein Structure Analysis by Mass Spectrometry" *Methods in Enzymology* 271:351-377 (1996)

Examiner

Date Considered

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.